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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,967	01/15/2002	Kevan M. Shokat	051538-5001-01	3019

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EXAMINER

WEBER, JON P

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 03/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/044,967

Applicant(s)

SHOKAT, KEVAN M.

Examiner

Jon P Weber, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 61-76 is/are pending in the application.
- 4a) Of the above claim(s) 4-6 and 61-73 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 74-76 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/15/02</u> . | 6) <input type="checkbox"/> Other: _____  |

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*Status of the Claims*

Claims 1-6 and 61-76 have been presented for examination.

*Election/Restrictions*

Applicant's election **with** traverse of Group I, claims 1-3 in the Paper filed 31 December 2003 is acknowledged. The traversal is on the ground(s) that Groups I and IV are related as genus-species. This is found persuasive. Restriction between Groups I and IV is withdrawn.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement between additional Groups II and III, the election has been treated as an election **without** traverse (MPEP § 818.03(a)) with respect to these groups.

Claims 4-6 and 61-73 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group, there being no allowable generic or linking claim. Election was made effectively **without** traverse. It is suggested that the non-elected claims be canceled in response to this Office action to expedite prosecution.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-3 and 74-76 remain to be considered on the merits.

*Claim Rejections - 35 USC § 112/101*

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 and 74-76 are rejected under 35 U.S.C. 101 as lacking credible utility, and under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1-3 and 74-76 are also rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is claimed that there exist inhibitors for enzymes in general (claims 1-3) and protein kinases in particular (claims 74-76) for which the catalytic activity of a wild type enzyme is not inhibited but the activity of a mutant enzyme is inhibited. The specification has been scoured for evidence of such inhibitors, particularly the pages 7-9 and 88-94 as directed in the response of 31 December 2003. No such evidence is present. What is presented is evidence that inhibitors can be found which exhibit selectivity for a mutant over a wild type of specified orders of magnitude in the value for  $K_i$ . Exhibiting selectivity is not the same thing mathematically or philosophically as exhibiting zero versus one hundred percent inhibition. It is known in the art that the inhibition of enzymes is an equilibrium-binding phenomenon represented by the phenomenological measured value of  $K_i$ . Selective inhibitors for one enzyme over another are known in the art (see,

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for example, Bishop et al., 1998; Bishop et al., 1999, J Am Chem Soc; Bishop et al., 1999, Pharmacol Ther; Faltynek et al., 1995; Hanke et al., 1996; Liu et al. 1999; and Tapley et al., 1992). This is not the issue. The issue is the absolute and extreme language of the claim. Further, the metes and bounds of compounds encompassed by the claims are unknown. The compounds allegedly encompassed by the claims are essentially unsearchable.

Claims 1 and 74 recite the term "mutant enzyme" which is confusing because all enzymes have evolved from previous versions by means of accumulated mutations according to neodarwinian evolutionary theory. Are the enzymes in different organisms that have the same function and purpose but different sequences to be considered mutants within the scope of the claims? Are isoenzymes having different sequences but serving the same function and purpose to be considered mutants (e.g., L-LDH and H-LDH; see the IUBMB definitions at <http://www.chem.qmul.ac.uk/iubmb/misc/isoen.html>)? Do the claims, or only specific ones encompass all mutants? What are the metes and bounds?

Finally, claims 1 and 74 assert that the wild type and mutant enzymes are functionally identical. This is impossible if they are inhibited differently. Inhibition is considered a property or function of the enzyme. Accordingly, the asserted utility is not only indefinite but incredible on its face.

### ***Claim Rejections - 35 USC § 103/102***

Given the rejections above, and the general unsearchable nature of the claims, it is not reasonable or possible to reject the claims as presented over the prior art. Su et al. (US 6,162,613) is cited as a relevant prior art reference.

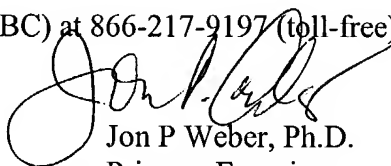
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No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P Weber, Ph.D. whose telephone number is 571-272-0925. The examiner can normally be reached on daily, off 1st Fri, 9/5/4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jon P Weber, Ph.D.  
Primary Examiner  
Art Unit 1651

JPW  
10 March 2004